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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,836	07/10/2001	Domenico Valerio	3837.1US	8961
24247	7590	08/19/2004	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			FALK, ANNE MARIE	
			ART UNIT	PAPER NUMBER

1632

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Advisory Action

Application No.

09/901,836

Applicant(s)

VALERIO ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☒ they raise the issue of new matter (see Note below);
 - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-15 and 21-24.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Anne-Marie Falk
 Anne-Marie Falk, Ph.D.
 Primary Examiner
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PTOL-303 Continuation Sheet**Continuation of 2. NOTE:**

The proposed amendment to Claim 14 raises new issues that would require new grounds of rejection under 35 U.S.C. 112, first paragraph, because the claim now recites “providing the capsid or envelope of said virus with the first member of the specific binding pair” which includes new matter. The claim now covers viruses constructed by externally providing the first member of the specific binding pair after the capsid or envelope has already formed, but the specification does not provide support for this manner of modifying the viral capsid or envelope. The specification only teaches capsid/envelope modification by recombinant expression of antigens that insert into the viral capsid or envelope.

Thus, the proposed amendment introduces new matter into the claims.

Continuation of 5. does NOT place the application in condition for allowance because:

Applicants argue that the negative limitation introduced into the claims does not represent new matter. The negative limitation introduced in the amendment filed March 25, 2004 recites “and said first member of the specific binding pair not being a viral antigen naturally expressed on said delivery vehicle” (see Claims 1 and 8). At page 7, paragraph 1 of the response (filed 7/19/04), Applicants argue that “it is clear from the specification that a native viral antigen is not contemplated as the first member of the specific binding pair.” This is obviously not true, because not only does the specification contemplate using a native viral antigen as the first member of the specific binding pair, the issued claims specifically recite it. See Claim 1 of issued patent USPN 6,261,554 which recites “wherein said first member of the specific binding pair is naturally or recombinantly expressed on said capsid or envelope exterior.” While the invention described in the specification **includes** the use of a native viral antigen as the first member of the

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specific binding pair it does not contemplate a scope where the use of native viral antigen is excluded. The MPEP specifically states that “[a]ny negative limitation or exclusionary proviso must have basis in the original disclosure” (MPEP § 2173.05(i)).

Applicants’ arguments have been fully considered, but are not deemed persuasive.

The rejections are maintained for reasons of record.